

# Clinical study carried out to investigate the efficacy of two probiotic formulates on irritable bowel syndrome

<b>Submission date</b> 18/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Irritable bowel syndrome (IBS) is a common, long-term disorder of the digestive system. It is part of a group of disorders called functional bowel disorders, as it affects the way the bowel (intestines) functions. IBS is associated with a number of digestive symptoms such as abdominal pain, diarrhoea, constipation and flatulence, which vary from person to person. The use of probiotics (live bacteria that are good for health as they replenish "good" bacteria that help the digestive system to work properly) has been shown to have beneficial effects on the health of people with IBS. The aim of this study is to compare two different probiotic mixtures in their effectiveness at treating irritable bowel syndrome with constipation (IBS-C).

### Who can participate?

Adults with IBS-C.

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group take capsules containing the first probiotic mix, which contains the bacteria *Lactobacillus acidophilus* and *Lactobacillus reuteri*, once a day for 60 days. Those in the second group group take capsules containing the first probiotic mix, which contains the bacteria *Lactobacillus plantarum*, *Lactobacillus rhamnosus* and *Bifidobacterium animalis* subspecies *lactis*, once a day for 60 days. Those in the third group take capsules containing a placebo (dummy) once a day for 60 days. All participants provide stool samples at the start of the study and then again after 10, 30, 60 and 90 days in order to measure the composition of the bacteria in the gut. At the same times, participants also complete a questionnaire about the IBS-C related symptoms they are having.

### What are the possible benefits and risks of participating?

Participants who take the probiotic mixtures may benefit from an improvement to their IBS symptoms. There are no notable risks involved with taking part in this study.

### Where is the study run from?

Farcoderm Clinic (Italy)

When is the study starting and how long is it expected to run for?  
July 2013 to January 2015

Who is funding the study?  
Ministry of Education, Universities and Research (Italy)

Who is the main contact?  
Dr Anela Michelotti

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Angela Michelotti

**Contact details**  
Farcoderm S.R.L.  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
MI.02.DS.L\_2013/PROBIOPLUS 4 FOOD

## Study information

**Scientific Title**  
Effects of multispecies probiotic supplementation on irritable bowel syndrome: a randomized, double-blind, placebo-controlled trial

**Study objectives**  
The aim of this study is to compare the clinical efficacy of two multispecies probiotic formulates, in particular their beneficial role in the functional bowel disorders will be state in comparison with a placebo.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Randomized double-blind three-arm placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Irritable bowel syndrome associated constipation (IBS-C)

**Interventions**

For the study 150 adult subjects, diagnosed with irritable bowel syndrome associated to constipation (IBS-C) were enrolled and divided in three groups (F\_1, F\_2, F\_3). Each group received a daily oral administration of different probiotic mixtures (for a total period of 60 days). Participants are randomly allocated to one of three groups:

Group 1: Participants receive probiotics mix F\_1 (Lactobacillus acidophilus and Lactobacillus reuteri) capsules to take once daily for 60 days.

Group 2: Participants receive probiotics mix F\_2 (Lactobacillus plantarum, Lactobacillus rhamnosus and Bifidobacterium animalis subsp. lactis) capsules to take once daily for 60 days.

Group 3: Participants receive a placebo in the form of mix F\_3 capsules to take once daily for 60 days.

Participants in all groups are followed for a further period of 30 days after a follow-up period from the last ingestion of the tested products; during this period they doesn't take anything.

**Intervention Type**

Supplement

**Primary outcome measure**

1. IBS-C symptoms are measured using the IBS-C questionnaire of related symptoms, which consists of five items (bloating, abdominal pain, constipation, abdominal cramps and flatulence) scored on a 10-point Visual Analogue Scale (VAS) at baseline, 10, 30 and 60 days
2. Gut colonization is determined through fecal microbiological analyses using species-specific qPCR on stool samples collected at baseline, 10, 30 and 60 days

## **Secondary outcome measures**

Maintenance of the obtained effects are measured using IBS-C symptoms questionnaire  
microbiological analyses performed by species-specific qPCR 30 days after the last product(s) intake.

## **Overall study start date**

05/07/2013

## **Completion date**

30/01/2015

# **Eligibility**

## **Key inclusion criteria**

1. Aged between 18 and 65 years old
2. Suffering from Irritable Bowel Syndrome with constipation (IBS-C)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

150

## **Key exclusion criteria**

1. Pregnancy or intention to become pregnant during the study period
2. Lactation
3. Food intolerances/allergy
4. Known history of gastro-intestinal disorders
5. Chronic or acute gastrointestinal disorders
6. Participation in another similar study
7. Unwillingness or inability to comply with the study protocol requirements
8. Currently using food supplements or drugs containing actives having an influence on gastro-intestinal physiology

## **Date of first enrolment**

01/09/2013

## **Date of final enrolment**

01/10/2014

# **Locations**

## Countries of recruitment

Italy

## Study participating centre

**Farcoderm Clinic (Farcoderm Poliambulatorio)**

Via Mons. Angelini, 21

San Martino Siccomario (PV)

Italy

27028

## Sponsor information

### Organisation

Farcoderm S.R.L.

### Sponsor details

Via Mons. Angelini, 21

San Martino Siccomario

Italy

27028

### Sponsor type

Other

## Funder(s)

### Funder type

Government

### Funder Name

Ministero dell'Istruzione, dell'Università e della Ricerca

### Alternative Name(s)

Ministry of Education, University and Research, Ministry of Education, Universities and Research, Italian Ministry for Universities and Research, Italian Ministry for Education, University and Research, Italian Ministry of Education, MIUR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

**Location**

Italy

## Results and Publications

**Publication and dissemination plan**

Planned publication in BioMed Research International (Hindawi Publishing Corporation).

**Intention to publish date**

31/05/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2016		Yes	No